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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,157	06/16/2006	Viktor Menart	33581-US-PCT	5099

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EXAMINER	
WOODWARD, CHERIE MICHELLE	

ART UNIT	PAPER NUMBER
1647	

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03/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/583,157	**Applicant(s)** MENART ET AL.	
	Examiner CHERIE M. WOODWARD	**Art Unit** 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 February 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *24 February 2010*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-4 and 6-12*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647

Continuation of 11. does NOT place the application in condition for allowance because: Applicant has cancelled claim 5 and move the subject matter of claim 5 into claim 1. Applicant has also cancelled withdrawn claims 14-16. Applicant has amended the dependency of claim 6. It is noted that the status identifier for claim 12 is improper. Claim 12 should be indicated as previously presented, since it appears to be the same claim previously presented. However, its current status identifier is "currently amended." The claim amendments filed 2/24/2010 have been entered. Claim rejections drawn to cancelled claim 5 are withdrawn as moot in light of the cancellation of the claim. However, all rejections over claim 5 are now applicable over amended claim 1 for the reasons of record. Applicant argues that the Miyazawa '416 patent, the Menart '124 publication.Applicant's argument is not persuasive. See the pin citations in the Office Action mailed 8/19/2008, especially at p. 2. Applicant defines an NDSB at p. 3 of the specification as a sulphobetaine that does not form micelles in water solution. The compositions of the cited art meet this limitation along with the structrual limitations of the NDSBs recited in claim 1, as amended. Applicant argues that the Menart '124 publication does not teach the composition athat is suitable for parenteral administration, as required by the amended claims. Applicant's argument has been fully considered, but it is not persuasive. The amended claims read on a composition of matter that is suited for pharmaceutical administration. The Menart '124 publication teaches compositions and methods of producting G-CSF using non-classical inclusion bodies and solubulizing those inclusion bodies in a gentler, less-toxic manner than ordinarily used in the art (see pages 2-3). Menart states that "[i]n most cases solubilisation of classical inclusion bodies requries the use of strong detergents which are toxic and are non-nature friendly and are serious environmental pollutants. Their use is also uneconomical because safe removal after the end of the process is an additional cost and is time consuming" (pp. 2 to 3). By using NDSB in making a G-CSF pharmaceutical composition, Menart teaches that you do not have to remove any remaining NDSB at the end of the process, resulting in a more economical, safe, environmentally friends, less-toxic, and time-saving end-product. Menart teaches pharmaceutical compositions in claim 37 and Example 12 (p. 34). Accordingly, the compositions taught by Menart would have NDSBs in the final pharmaceutical composition because the compositions were not subject to post-manufacture removal of the NDSBs. Vuilliard need not teach what is taught by Menart.